

FORM PTO-1449 FEB 24 2004 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NIH211.001C1	APPLICATION NO. 10/646,628
		APPLICANT Moss et al.	
		FILING DATE August 22, 2003	GROUP 1645

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
RZ	1.	5,849,304	12/15/1998	Moss et al.	—	—	
RZ	2.	5,185,146	02/09/1993	Altenburger	—	—	

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
RZ	3.	WO 01/47955 A2	07/05/2001	PCT	—	—	

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
RZ	4.	Allen, T.M. et al., 2000 "Induction of AIDS virus-specific CTL activity in fresh, unstimulated peripheral blood lymphocytes from rhesus macaques vaccinated with a DNA prime/modified vaccinia virus Ankara boost regimen" <i>J. Immunol.</i> 164:4968-4978.
RZ	5.	Amara, R.R. et al., 2001 "Control of a Mucosal Challenge and Prevention of AIDS by a Multiprotein DNA/MVA Vaccine" <i>Science</i> 292: 69-74.
RZ	6.	Barouch, D.H. et al., 2000 "Control of viremia and prevention of clinical AIDS in rhesus monkeys by cytokine-augmented DNA vaccination" <i>Science</i> 290:486-492.
RZ	7.	Egan, M.A. et al., 2000 "Simian immunodeficiency virus (SIV) gag DNA-vaccinated rhesus monkeys develop secondary cytotoxic T-lymphocyte responses and control viral replication after pathogenic SIV infection" <i>J. Virol.</i> 74:7485-7495.
RZ	8.	Gomez, C.E et al., 2001 "Recombinant proteins produced by vaccinia virus vectors can be incorporated within the virion (IMV form) into different compartments" <i>Arch Virol.</i> 146(5):875-892.
RZ	9.	Gorelick, R.J. et al., 1999 "Nucleocapsid protein zinc-finger mutants of Simian Immunodeficiency Virus strain Mne produce virions that are replication defective <i>in vitro</i> and <i>in vivo</i> " <i>Virology</i> 253:259-270.
RZ	10.	Goulder, P.J. et al., 1999 "Anti-HIV cellular immunity: recent advances towards vaccine design" <i>AIDS (Suppl. A)</i> 13:S121-S136.
RZ	11.	Hirsch, V.M. et al., 1995 "Limited virus replication following SIV challenge of macaques immunized with attenuated MVA vaccinia expressing SIVsm env and gag-pol" <i>Vaccines</i> 95:195-200.
RZ	12.	Hofmann-Lehmann, R. et al., 2000 "Sensitive and robust one-tube real-time reverse transcriptase-polymerase chain reaction to quantify SIV-RNA load: comparison of one- versus two-enzyme systems" <i>AIDS Res. Hum. Retroviruses</i> 16:1247-1257.

EXAMINER <i>RZ</i>	DATE CONSIDERED <i>9/13/05</i>
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.	

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
RL	13. Karacostas, V. et al., 1989 "Human immunodeficiency virus-like particles produced by a vaccinia virus expression vector" <i>PNAS USA</i> 86:8964-8967.
RL	14. Karlsson, G.B. et al., 1997 "Characterization of molecularly cloned simian-human immunodeficiency viruses causing rapid CD4 ⁺ lymphocyte depletion in rhesus monkeys" <i>J. Virol.</i> 71:4218-4225.
RZ	15. Lechner, F. et al., 2000 "Analysis of successful immune responses in persons infected with hepatitis C virus" <i>J. Exp. Med.</i> 191:1499-1512.
RL	16. Mellors, J.W. et al., 1996 "Prognosis in HIV-1 infection predicted by the quantity of virus in plasma" <i>Science</i> 272:1167-1170.
RL	17. Montefiori, D.C. et al., 1998 "Neutralizing antibodies in sera from macaques infected with chimeric Simian-Human Immunodeficiency Virus containing the envelope glycoproteins of either a laboratory-adapted variant or a primary isolate of Human Immunodeficiency Virus type 1" <i>J. Virol.</i> 72:3427-3431.
RL	18. Montefiori, D.C. et al., 1988 "Evaluation of antiviral drugs and neutralizing antibodies to Human Immunodeficiency Virus by a rapid and sensitive microtiter infection assay" <i>J. Clin. Microbiol.</i> 26:231-235.
RL	19. Moss, B. et al., 2000 "Retroviruses of human AIDS and related animal diseases" in: Colloque des Cent Gardes, 12th, Paris, France, Oct. 25-27, 1999, Meeting Date 1999, 105-107, Eds. M. Girard & B. Dodet, Editions Scientifiques et Medicales Elsevier, Paris, Fr. (Abstract).
RL	20. Ourmanov I. et al., 2000 "Recombinant modified vaccinia virus Ankara expressing the surface gp120 of simian immunodeficiency virus (SIV) primes for a rapid neutralizing antibody response to SIV infection in macaques" <i>J Virol.</i> 74:2960-2965.
RL	21. Ourmanov, I. et al., 2000 "Comparative efficacy of recombinant modified vaccinia virus Ankara expressing Simian Immunodeficiency Virus (SIV) Gag-Pol and/or Env in macaques challenged with pathogenic SIV" <i>J. Virol.</i> 74:2740-2751.
RL	22. Power, C.A et al., 1999 "A valid ELISPOT assay for enumeration of <i>ex vivo</i> , antigen-specific, IFN γ -producing T cells" <i>J. Immunol. Methods</i> 227:99-107.
RL	23. Quinn, T.C. et al., 2000 "Viral load and heterosexual transmission of Human Immunodeficiency Virus type 1" <i>N. Engl. J. Med.</i> 342:921-929.
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RL	25. Robinson, H.L. et al., 1999 "Neutralizing antibody-independent containment of immunodeficiency virus challenges by DNA priming and recombinant pox virus booster immunizations" <i>Nature Med.</i> 5:526-534.
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EXAMINER	<i>Robert L. Zorn</i>	DATE CONSIDERED	<i>9/13/05</i>
*EXAMINER: INITIAL IF CITATION CONSIDERED. WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.			

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RZ	27.	Staprans, S. et al., 1996 "Quantitative methods to monitor viral load in Simian Immunodeficiency Virus infections" in: <i>Viral Genome Methods</i> , K. Adolph, Ed. (CRC Press, Boca Raton, FL, 1996), pp. 167-184.
RZ	28.	Waldrop, S.L. et al., 1997 "Determination of antigen-specific memory/effector CD4 ⁺ T cell frequencies by flow cytometry: evidence for a novel, antigen-specific homeostatic mechanism in HIV-associated immunodeficiency" <i>J. Clin. Invest.</i> 99:1739-1750.

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EXAMINER	<i>Robert Ziem</i>	DATE CONSIDERED	<i>9/13/05</i>
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Multiple sheets used when necessary)

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SHEET 1 OF 1

Application No.	10/646,628
Filing Date	August 22, 2003
First Named Inventor	Moss, Bernard
Art Unit	1645
Examiner	Robert A. Zeman
Attorney Docket No.	NIH211.001C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
rz	1	WO 91/07425	05/30/1991	Oncogen Limited Partnership		
rz	2	WO 01/92470 A2	12/06/2001	Emory University		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
rz	3	Supplementary Partial European Search Report for co-pending European Application Serial No. 02 72 1259.	
rz	4	EARL, P.L. et al. "Comparison of vaccine strategies using recombinant env-gag-pol MVA with or without an oligomeric env protein boost in the SHIV rhesus macaque model" Virology (2002) 294:270-281.	
rz	5	GIRARD, M. et al. "New prospects for the development of a vaccine against human immunodeficiency virus type 1. An overview" C.R. Acad. Sci. Paris, Sciences de la Vie/Life Sciences (1999) 322:959-966.	
rz	6	MEN, R. et al. "Immunization of rhesus monkeys with a recombinant of modified vaccinia virus Ankara expressing a truncated envelope glycoprotein of dengue type 2 virus induced resistance to dengue type 2 virus challenge" Vaccine (2000) 18:3113-3122.	

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Examiner Signature	<i>Robert A. Zeman</i>	Date Considered	7/13/05
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T¹ - Place a check mark in this area when an English language Translation is attached.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 12804-027001	Application No. 10/646,628
Information Disclosure Statement by Applicant <small>MAY 23 2005 (37 CFR §1.98(b))</small>		Applicant Bernard Moss et al.	
		Filing Date August 22, 2003	Group Art Unit 1645

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
RZ	AA	5,795,577	8/18/1998	Kieny et al.	424	208.1	
	AB						

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
RZ	AC	WO 99/63098	12/9/1999	WIPO				
RZ	AD	WO 89/12095	12/14/1989	WIPO				
RZ	AE	EP 0 538 496	8/26/1991	EPO				

Other Documents (include Author, Title, Date, and Place of Publication)

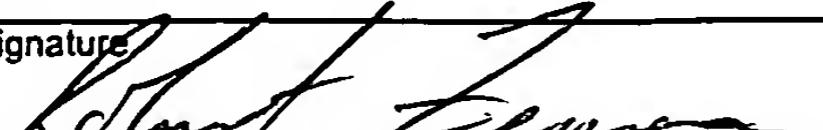
Examiner Initial	Desig. ID	Document
RZ	AF	Belyakov et al., "Induction of a Mucosal Cytotoxic T-Lymphocyte Response by..." J. of Virology 72(1):8264-8272, 1998.
RZ	AG	Davison et al., "Structure of Vaccinia Virus Early Promoters" J. Mol. Biol. 210:749-769, 1989.
RZ	AH	Hanke et al., "Enhancement of MHC class I-restricted peptide-specific T cell induction..." Vaccine 16(5):439-445, 1998.
RZ	AI	Hanke et al., "Lack of toxicity and persistence in the mouse associated with administration of candidate..." Vaccine 21:108-114, 2002.
RZ	AJ	Hanke et al., "Development of a DNA-MVA/HIVA vaccine for Kenya" Vaccine 20:1995-1998, 2002.
RZ	AK	Hanke et al., "Pre-clinical development of a multi-CTL epitope-based DNA prime MVA boost vaccine for AIDS" Immunology Letters 66:177-181, 1999.
RZ	AL	Hanke et al., "Effective induction of HIV-specific CTL by multi-epitope using gene gun..." Vaccine 17:589-596, 1999.
RZ	AM	Hanke et al., "Immunogenicities of intravenous and intramuscular administrations of modified vaccinia..." J. of General Virology 79:83-90, 1998.
RZ	AN	Haffar et al., "The Carboxy Terminus of Human Immunodeficiency Virus Type I gp160..." J. of Virology 64(6):3100-3103, 1990.
RZ	AO	Masternak et al., "cis- and trans-Acting Elements Involved in Reactivation of Vaccinia Virus Early Transcription" J. of Virology 70(12):8737-8746, 1996.
RZ	AP	Wee et al., "A DNA/MVA-based candidate human immunodeficiency virus vaccine for Kenya induces..." J. of General Virology 83:75-80, 2002.
RZ	AQ	Wyatt et al., "Development of a replication-deficient recombinant vaccinia virus vaccine effective against..." Vaccine 14(15):1451-1458, 1996.
RZ	AR	Wyatt et al., "Priming and boosting immunity to respiratory syncytial virus by recombinant replication-defective..." Vaccine 18:392-397, 2000.

Examiner Signature <i>Robert Egan</i>	Date Considered <i>9/13/07</i>
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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AUG 01 2005 Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Bernard Moss et al.	
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U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
RZ	AA	5,169,763	12/1992	Kieny et al.	—	—	
RZ	AB	5,256,767	10/1993	Salk and Carlo	—	—	
RZ	AC	5,445,953	08/1995	Dorner et al.	—	—	
RZ	AD	5,494,807	02/1996	Paoletti et al	—	—	
RZ	AE	5,589,466	12/1996	Felgner et al.	—	—	
RZ	AF	5,593,972	01/1997 03/1999	Weiner et al.	—	—	
RZ	AG	5,614,404	03/1997	Mazzara et al.	—	—	
RZ	AH	5,676,950	10/1997	Small et al.	—	—	
RZ	AI	5,736,368	04/1998	Mazzara et al.	435	320.1	
RZ	AJ	5,741,492	04/1998	Hurwitz and Owens	—	—	
RZ	AK	5,747,324	05/1998	Mazzara et al.	—	—	
RZ	AL	5,747,338	05/1998	Giese and Escobedo	—	—	
RZ	AM	5,756,103	05/1998	Paoletti et al.	424	160.1	
RZ	AN	5,766,599	06/1998	Paoletti et al.	435	5	
RZ	AO	5,817,637	10/1998	Weiner et al.	435	456	
RZ	AP	5,846,946	12/1998	Huebner et al.	514	44	
RZ	AQ	5,853,725	12/1998	Salk and Carlo	424	208.1	
RZ	AR	5,858,775	1/1999	Johnson, Phillip R.	435	320.1	
RZ	AS	5,863,542	01/1999	Paoletti et al.	—	—	
RZ	AT	5,879,925	03/1999	Rovinski et al.	—	—	
RZ	AU	5,911,989	6/1999	Katinger et al.	424	160.1	
RZ	AV	5,928,930	07/1999	Salk and Carlo	—	—	
RZ	AW	5,985,641	11/1999	Haynes et al.	—	—	
RZ	AX	6,051,410	04/2000	Mazzara et al.	—	—	
RZ	AY	6,077,662	6/2000	Compans et al.	435	5	
RZ	AZ	6,080,408	06/2000	Rovinski et al.	—	—	

Examiner Signature 	Date Considered 9/13/05
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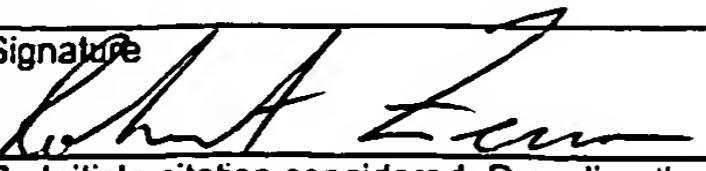
U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
RZ	AAA	6,086,891	07/2000	Hurwitz and Coleclough	—	—	
RZ	ABB	6,099,847	08/2000	Tobin and Gonda	—	—	
RZ	ACC	6,103,244	08/2000	Dorner et al.	—	—	
RZ	ADD	6,121,021	09/2000	Rovinski et al.	—	—	
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RZ	AFF	6,156,952	12/2000	Bryant et al.	800	11	
RZ	AGG	6,171,596	01/2001	Earl et al.	—	—	
RZ	AHH	6,201,663	04/2001	Eiji Yamaguchi et al.	—	—	
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RZ	AMM	6,306,625	10/2001	Jacobs et al.	—	—	
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Foreign Patent Documents or Published Foreign Patent Applications

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							Yes	No
RZ	APP	WO 97/27311	7/1997	WIPO				
RZ	AQQ	WO 98/56919	12/1998	PCT International				
RZ	ARR	WO 00/00216	01/2000	PCT International				
RZ	ASS	WO 01/02607	01/2001	PCT International				
RZ	ATT	WO 01/52886	07/2001	PCT International				
RZ	AUU	WO 01/82962	11/2001	PCT International				
RZ	AVV	WO 02/072754	9/2002	WIPO				

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RZ	AWW	WO 03/004657	1/2003	WIPO				

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Examiner Initial	Desig. ID	Document
RZ	AXX	Amara <i>et al.</i> , "Different Patterns of Immune Responses but Similar Control of a Simian-Human Immunodeficiency Virus 89.6P Mucosal Challenge by Modified Vaccinia Virus Ankara (MVA) and DNA/MVA Vaccines," <i>J. Virology</i> 76:7625-7631 (2002)
RZ	AYY	Andre <i>et al.</i> , "Increased immune response elicited by DNA vaccination with a synthetic gp120 sequence with optimized codon usage," <i>J. Virol.</i> , 72: 1497-1503, 1998.
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RZ	AAAA	Asakura <i>et al.</i> , "Induction of HIV-1 specific mucosal immune responses by DNA vaccination," <i>Scand. J. Immunol.</i> , 46: 326-330, 1997.
RZ	ABBB	Bachmann and Zinkernagel, "Neutralizing antiviral B cell responses," in <i>Ann. Rev. Immunol.</i> , 15: 235-270, 1997.
RZ	ACCC	Barouch <i>et al.</i> , "Reduction of Simian-human immunodeficiency virus 89.6P viremia in rhesus monkeys by recombinant modified vaccinia virus Ankara vaccination," <i>J. Virol.</i> , 75: 5151-5158, 2001.
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RZ	AEEE	Barry <i>et al.</i> , "Protection against mycoplasma infection using expression-library immunization," <i>Nature</i> , 377: 632-635, 1995.
RZ	AFFF	Berger, "HIV Entry and Tropism: the chemokine receptor connection," <i>AIDS</i> , 11(Suppl. A): S3-16, 1997.
RZ	AGGG	Benson <i>et al.</i> , <i>J. Virol.</i> , "Recombinant vaccine-induced protection against the highly pathogenic simian immunodeficiency virus SIV(mac251): dependence on route of challenge exposure," 72: 4170-4182, 1998.
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RZ	AIII	Bohm <i>et al.</i> , "DNA vector constructs that prime hepatitis B surface antigen-specific cytotoxic T lymphocyte and antibody responses in mice after intramuscular injection," <i>J. Immuno. Methods</i> , 193: 29-40, 1996.
RZ	AJJJ	Bohm <i>et al.</i> , "Routes of plasmid DNA vaccination that prime murine humoral and cellular immune responses," <i>Vaccine</i> , 16: 949-54, 1998.
RZ	AKKK	Bolivar <i>et al.</i> , "Construction and Characterization of New Cloning Vehicles: (II. A Multipurpose Cloning System)," <i>Gene</i> , 2: 95-113, 1977.

Examiner Signature <i>Robert Zemo</i>	Date Considered <i>9/13/05</i>
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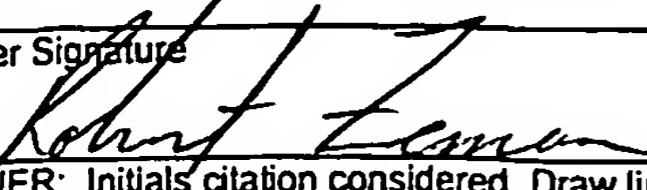
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Other Documents (include Author, Title, Date, and Place of Publication)			
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fz	ALLL	Boyer <i>et al.</i> , "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," <i>Nature Med.</i> , 3: 526-532, 1997.	
rz	AMMM	Boyle <i>et al.</i> , "Influence of cellular location of expressed antigen on the efficacy of DNA vaccination: cytotoxic T lymphocyte and antibody responses are suboptimal when antigen is cytoplasmic after intramuscular DNA immunization," <i>Int. Immunol.</i> , 9: 1897-1906, 1997.	
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rz	AQQQ	Calarota <i>et al.</i> , "Cellular cytotoxic response induced by DNA vaccination in HIV-1-infected patients," <i>Lancet</i> , 351: 1320-1325, 1998.	
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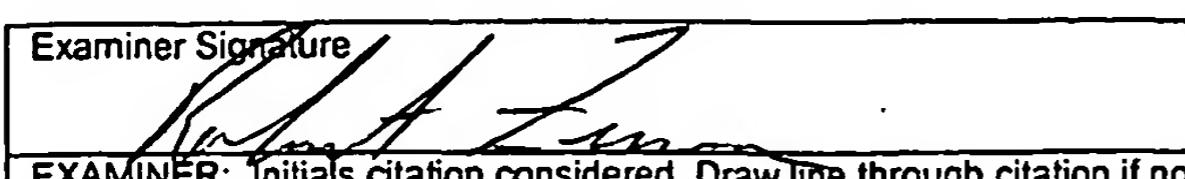
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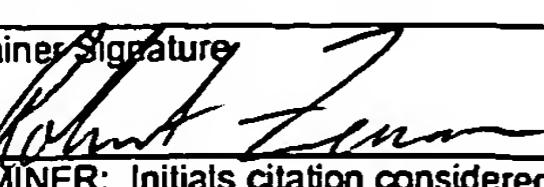
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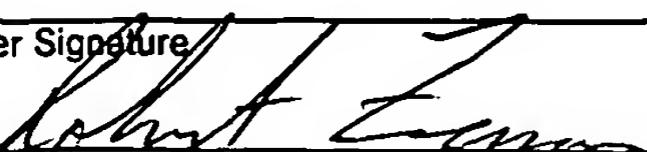
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Examiner Initial	Desig. ID	Document
RZ	RRRRRRR	Ulmer <i>et al.</i> , "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," <i>Science</i> 259: 1745-1749, 1993.
RL	ASSSSSSS	Villinger <i>et al.</i> , "Induction of Long-Term Protective Effects against Heterologous Challenge in SIVhu-Infected Macaques", <i>Virology</i> , 278:194-206, 2000.
RL	TTTTTTT	Wang <i>et al.</i> , "Mammalian cell/vaccinia virus expression vectors with increased stability of retroviral sequences in E.coli; production of feline immunodeficiency virus envelope protein," <i>Gene</i> 153:197-202 (1995).
RL	UUUUUUU	Watson <i>et al.</i> , "Plasma Viremia in Macaques Infected with Simian Immunodeficiency Virus: Plasma Viral Load Early in Infection Predicts Survival", <i>J. Virol.</i> , 71: 284-90, 1997.
RL	VVVVVVV	Wild <i>et al.</i> , "Polyvalent vaccination against hepatitis B surface and core antigen using a dicistronic expression plasmid," <i>Vaccine</i> , 16: 353-360, 1998.
RL	WWWWWWW	Wolff <i>et al.</i> "Direct Gene Transfer into Mouse Muscle in Vivo," <i>Science</i> , 247: 1465-1468, 1990.
RZ	XXXXXXX	Wu <i>et al.</i> , "Deoxyribonucleic Acid Vaccines Encoding Antigens With Rapid Proteasome-Dependent Degradation Are Highly Efficient Inducers of Cytolytic T Lymphocytes," <i>J. Immunol.</i> , 159: 6037-6043, 1997.
RL	YYYYYYY	Wyand <i>et al.</i> , "Protection by live, attenuated simian immunodeficiency virus against heterologous challenge," <i>J. Virol.</i> , 73: 8356-8363, 1999.
RL	AZZZZZZ	Wyatt <i>et al.</i> , "Marker Rescue of the Host Range Restriction Defects of Modified Vaccinia Virus Ankara," <i>Virology</i> , 251:334-42, 1998.
RZ	AAAAAAA	Xiang <i>et al.</i> , "Manipulation of the Immune Response to a Plasmid-Encoded Viral Antigen by Coinoculation with Plasmids Expressing Cytokines," <i>Immunity</i> , 2: 129-135, 1995.
RL	BBBBBBB	Yamamoto <i>et al.</i> , "Highly sensitive qualitative and quantitative detection of reverse transcriptase activity: optimization, validation, and comparative analysis with other detection systems," <i>J. Virol. Methods</i> , 61: 135-143, 1996.
RL	CCCCCCC	Yang and Walker, "CD8+ cells in human immunodeficiency virus type I pathogenesis: cytolytic and noncytolytic inhibition of viral replication," <i>Adv. Immunol.</i> , 66: 273-311, 1997.
RL	DDDDDDD	Zajac <i>et al.</i> , "Viral Immune Evasion Due to Persistence of Activated T Cells Without Effector Function", <i>J. Exp. Med.</i> , 188:2205-13, 1998.

Examiner Signature 	Date Considered 9/13/05
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